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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,730	04/23/2001	Michael R. Hufford	IVQ-003	4534
959	7590	10/04/2005	EXAMINER	
LAHIVE & COCKFIELD, LLP.			SMITH, TRACI L	
28 STATE STREET			ART UNIT	
BOSTON, MA 02109			PAPER NUMBER	
			3629	

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

*KL*

## Office Action Summary

Application No.

09/840,730

Applicant(s)

HUFFORD ET AL.

Examiner

Traci L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                    |                                                                             |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____                                                |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____                                                                        | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. This action is in response to papers filed on April 23, 2001.
2. Claims 1-51 are pending.
3. Claims 1-51 are rejected.

#### ***Claim Rejections - 35 USC § 112***

4. Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 31 is directed to a duration of time, however, examiner is unable to understand what points the duration is between. Is it the duration in which the user is in the diary or is it the duration between the last time of use and the current time.

#### ***Claim Rejections - 35 USC § 102***

#### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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6. Claims 1-32 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,362,440 B1 Karidis et al. Flexibility Interfaceable Portable Computing Device.

7. As to claims 1, 22 and 26 Karidis teaches a system and apparatus with a paper for to record data(Fig. 10 I. 44-46) and an electronic instrument for generating a record of diary use(C.9 I. 61-65).

8. As to claims 2, 23, 25 and 27 Karidis teaches an interface with instrument and computer(C. 6 I. 45-55).

9. As to claim 3 and 28 Karidis teaches sensors detecting use(C. 9 I. 67 & C. 10 I. 1-5).

10. As to claim 4-7, 10-11 and 13 teaches a detection of various events via various sensors and detection methods. The fact that the sensors are used to detect specific events such as opening or closing is non-functional descriptive data. Thus, this descriptive material will not distinguish the claimed invention from the prior art in terms of patentability, see in re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 44(Fed. Cir. 1983); In re Lowry, 32 F.3d 1579, 32 USPQ 2d 1031(Fed. Cir. 1994).

11. As to claims 8, 15-18 and 29-32 Karidis teaches the electronic record recording time and date of when the instrument was used(C. 10 I. 18-22).

12. As to claims 9 and 21 Karidis teaches sensors located under the paper and out of sight of user.

13. As to claim 12 Karidis teaches using a pen with a sensor.(C. 9 I. 10-15)

14. As to claim 14 Karidis teaches storing the records.(C. 6 I. 28-30).

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15. As to claims 19-20 electronic instrument is visible and has a display.(Fig. 13 Ref. 202)

16. As to claim 24 Karidis teaches cable connecting to the computer(C. 6 I. 39-41)

17. As to claim 51 teaches a method providing a paper form(Fig. 10 I. 44-46) and electronic instrument tracking use(C. 9 I. 61-65) as well as connecting the instrument to the paper form to record when paper form is used(C. 10 I. 1-5).

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 33, 38-39 rejected under 35 U.S.C. 102(b) as being anticipated by Straka et al; Patient Self Reporting of Compliance Does not Correspond with Electronic Monitoring: An Evaluation Using Isosorbide Dinitrite as a Model Drug.

20. As to Claim 33 Straka teaches detecting an event related to an entry in a diary(Pg 2 C. 2 I. 5-8) and creating an electronic record of event(Pg. 1 I. 13-14).

21. As to claims 38-39 the characteristic is a date and time of event(Pg. 1 I. 14).

### ***Claim Rejections - 35 USC § 103***

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

24. Claims 34-37 and 40-41 rejected under 35 U.S.C. 103(a) as being unpatentable over by Straka et al; Patient Self Reporting of Compliance Does not Correspond with Electronic Monitoring: An Evaluation Using Isosorbide Dinitrite as a Model Drug.as applied to claims 33 and 38-39 above, and further in view of US Patent 6,362,440.

25. As to claims 34-37 Straka teaches electronic monitoring of use according to a paper diary, however, Straka fails to teach detecting when the paper diary is used. Karidis teaches sensors detecting when user writes on the paper diary(C. 9 l. 50-55). It would have been obvious to one skilled in the art at the time of invention to combine the teachings of Karidis with Straka so as to require the user to only use one apparatus when logging data. Although the reference fails to teach what the event is that is detected these differences are only found in the nonfunctional descriptive material and are not functionally involved in the steps recited. The steps would be performed regardless of the type of event describe and the types of events are not further employed in the remaining steps. Thus, this descriptive material will not distinguish the claimed invention from the prior art in terms of patentability, see in re Gulack, 703 F.2d

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1381, 1385, 217 USPQ 401, 44(Fed. Cir. 1983); In re Lowry, 32 F.3d 1579, 32 USPQ 2d 1031(Fed. Cir. 1994).

26. As to claims 40-41 Hyland fails to teach using the paper diary to record event and time stamp it. However Straka teaches time stamping a record when user writes on paper portion of instrument.(C. 10 l. 18-21). It would have been obvious to one skilled in the art at the time of invention to combine the teachings of Straka with Hyland to enable an accurate step of record keeping of an event.

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

28. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

29. Claims 42-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyland et al: Diary Keeping in Asthma: Comparison of Written and Electronic methods; further in view of US Patent 6,362,440 B1 Karidis et al. Flexibility Interfaceable Portable Computing Device.

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30. As to claim 42 and 47 Hyland teaches a method for generating electronic records of an event concerning a diary entry(Pg. 1 C. 2 ¶ 3). However, Hyland fails to teach the apparatus used as one unit that allows the paper forms and record creation. Straka teaches an apparatus which allows user to write on paper and use is detected via the connect electronic device(C. 8 l. 54-60). It would have been obvious to one skilled in the art at the time of invention to combine the teaches of Straka with Hyland so as to ensure a better quality of diary records.

31. As to claims 43 and 48 Hyland fails to teach the creating a record when the diary is used. However, Straka teaches time stamping the electronic record of use.(C. (C.10 l. 18-21). It would have been obvious to one skilled in the art at the time of invention to combine the teachings of Straka with Hyland so as to have an accurate account of when the detected event took place.

32. As to claims 44 and 49 Hyland teaches the user writing a the date in the diary( Pg 2 C. 1 l. 10-12).

33. As to claims 45-46 and 50 Hyland teaches when uses a comparison of electronic data with user entered data to determine compliance( Pg 2 C. 2 ¶ 2).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traci L. Smith whose telephone number is 572-272-6809. The examiner can normally be reached on Monday-Thursday 6:00 am-4:30 pm.

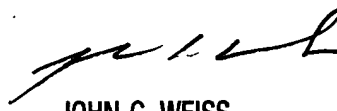
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss can be reached on 571-272-6812. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TLS



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